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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/516,320 | 12/13/2004 | Yasushi Nakada | 262891US0PCT | 3886 |

22850 7590 03/20/2007
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
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ALEXANDRIA, VA 22314

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| EXAMINER |
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SHIAO, REI TSANG

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 31 DAYS | 03/20/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 03/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/516,320

Applicant(s)

NAKADA ET AL.

Examiner

Rei-tsang Shiao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-8 are pending in the application.

Election/Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

3. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.
 - I. Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is T-588 thereof (compound A1, i.e., the variable R¹ represents heterocyclic group selected from benzothiazole thereof) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R³ and R⁴ form a piperidine); or drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is T-588 thereof (compound A1, i.e., the variable R¹ represents heterocyclic group selected from benzothiazole thereof) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making. If this group is elected, applicants are requested to elect a single species for the search purpose.

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- II. Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 2- [[3- (2-benzo[b]thiophen-5-yl-ethoxy)propyl] (methyl)amino] -1-ethanol.1/2 fumarate thereof (compound A2) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R^3 and R^4 form a piperidine); or drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 2- [[3- (2-benzo[b]thiophen-5-yl-ethoxy)propyl] (methyl)amino] -1-ethanol.1/2 fumarate thereof (compound A2) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making. If this group is elected, applicants are requested to elect a single species for the search purpose.
- III. Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 1-[3-(2-(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol thereof (compound A3) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R^3 and R^4 form a piperidine); or drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 1-[3-(2-(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol thereof (compound A3) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making. If this group is elected, applicants are requested to elect a single species for the search purpose.

- IV. Claims 1-8, in part, drawn to a pharmaceutical composition, containing compounds or ingredient (A) or (B) not encompassed in Groups I-III

Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, Part 1(b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art.

Annex B, Part 1(c), further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim which contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, Part 1(f) indicates the "Markush practice" of alternatives in a single claim. Part 1(f(i)) indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, Part 1(f)(i-iii), the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure which is responsible for the common activity (or property). Part 1(f(iv)) indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. Part 1(f(v)) indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a

single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see Schimada et al. CAS:127:362624. Moreover, The claimed compounds/compositions of the formula of claim 1 contains different common structures or different special technical features, i.e., compounds having various moieties (i.e., morpholine, piperidine or pyrrolidine). Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unit of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a burden on any examination of the claimed subject matter.

4. Applicants are advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Rei-tsang Shiao', with a stylized, cursive script.

Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

March 14, 2007